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(54) Title: MULTI–STAGE PROSTHESIS

(57) Abstract

A porous fluoropolymer article forms an artificial internal organ, for example, a vascular bypass, vascular access, or endovascular prosthesis. PTFE having a fibrous structure of nodes and fibers connecting the nodes together forms a wall with radial zones of differing porosity in a porous tube. In one aspect an integrated intrawall circumferential support adjacent to areas of variable porosity provides enhanced tunneling and cannulizability. In another aspect, the wall of a prosthesis has a region which modulates communication through the porosity of the wall. The prosthesis is unitary, but may be assembled in successive bodies which are coalesced, so that the porous microstructure changes distinctly at stages through the thickness dimension of the wall. One embodiment is formed entirely of fluoropolymer, and has at least one surface adapted to support tissue regeneration and ingrowth. The modulation region is a stratum of high water entry pressure that reduces pulsatile hydraulic pressure transmission, or locally alters fluid–born distribution of biological material through the wall and allows more natural gradients for tissue regeneration and growth in the outer region of the wall. In another aspect, the inner portion includes a radially expandable support body, which is enveloped within a cocoon. In a preferred construction, the support is a stent, and a tube of fluoropolymer such as PTFE passes through the interior of the stent body and is turned back upon itself over the stent to form a cuff. The assembly is then heated and the outer layer contacts and coalesces with the inner layer, closely surrounding the stent body within a folded envelope having a continuous and seamless end. An end portion of the tube may be expanded before folding back over the stent. The end portion, which becomes an exterior surface of the finished product, thus acquires a greater degree of porosity. Each end of the central tube may be so expanded, and folded back to seal all surfaces and both ends. The stent body itself may be a ring, or a short series of spaced–apart rings, or a wire or web, or a sheet possessing a number of apertures extending entirely through the sheet. The spaces or apertures are covered over or bridged by both the inner and outer polymer layers. The apertures, which may comprise under five to over eighty percent of the surface area of the stent, constitute regions or a grid of points through which the material is coalesced and continuously bonded, and around which strain is distributed by the support. These points or regions remain tacked together so expansion of the assembly does not delaminate the polymer or create flaps and pockets. In another embodiment, a two tube construction is cuffed and assembled into a similarly unitized and seamless stent. One tube is cuffed back, and the other tube covers the cuffed stent. In this embodiment both the tube thicknesses and porosities may differ substantially. For example the inner porosity may be selected to enhance blood flow or intimal regeneration, and the outer surface may have a porosity to encourage anchoring to external muscle tissue.